K100801

PROWESS

510(k) SUMMARY

As required by 21 CFR Part 807.92

JUN 18 2010

May 7, 2010

1. **Submitter:**

Prowess, Inc.
1844 Clayton Road
Concord, CA. 94520

Contact Person:

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Device Manufacturer:

Prowess, Inc.
1844 Clayton Road
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2. **Device Trade Name:** Puma

Classification Name: Medical charged-particle radiation therapy system (21 CFR § 892.5050), Product Code MUJ, Class II

Establishment Reg. No.: 2939248

Common Name: Radiation Therapy Record and Verify System
Oncology Information System

3. **Predicate Devices:**

a) Siemens Medical System's Lantis Treatstation – K972275

b) Varian Medical System's 4D Integrated Treatment Console (4DITC) – K091132

4. **Device Description**

Puma is a medical device, which allows the user to deliver radiation treatment on linear accelerator to a patient. The software has been developed to be a record and verify system that also manages oncology medical information in order to simplify the oncologist administrative tasks and to optimize the quality of patient treatment. It is a Windows® based system, which uses a single database that can be accessed by any Puma client station in the treatment facility. Additionally, Puma is capable of performing such functions as:

- Importing treatment plans in DICOM or RTP format
- Downloading of beams contained in the treatment plans to the linear accelerator
- Verifying that the beams from the treatment plan are correctly set up on the linear accelerator
- Recording treatments delivered by the linear accelerator
- Managing patient schedules
- Managing schedules for resources such as treatment machines and personnel
- Maintaining a central repository of treatment plans and records

5. Intended Use

The intended use of Puma is to allow the radiation therapist to deliver treatment to the patient via linear accelerator (linac). This entails selection of the patient, selection of the day's correct treatment for that patient, set up, and delivery of the treatment fields and recording of the treatment. Puma supports auto-sequencing, a process of automatically downloading a group of fields or segments from the record and verify system to the control of the linear accelerator sequentially, without user intervention. In addition, Puma also supports IMRT (Intensity Modulated Radiation Therapy), a process of shaping, modifying, and moving a beam around a target to maximize dose at the target and minimize the dose to normal structures.

6. Summary of Comparisons to Predicate Devices

Puma is substantially equivalent to the predicate devices, Siemens' Lantis Treatstation and Varian's 4DITC, for purposes of FDA clearance for commercial distribution, as demonstrated and documented in this premarket notification submission. It has the same intended use and indications for use. In addition, the rationalization for substantial equivalence is further evidenced through discussion of similar technological characteristics between Puma and the predicates, as well as test results, which prove that Puma is as safe and effective as the predicate devices.

7. Summary of Technological Considerations

Puma has many of the same technological characteristics as the predicate devices. There is a limited amount of distinguishing factors when comparing Puma to the predicates, and those features that are different do not affect safety or effectiveness. This is described in detail in Section VII: Substantial Equivalence Comparison.

8. Summary of Non-clinical Tests

A hazard analysis was completed for Puma. Methods for preventing such hazards were detailed (Section VIII). Verification and validation of the software was conducted in house according to the Verification and Validation (V&V) Protocol, *Puma Testing Protocol*. The V&V Protocol, and test results are included in Section IX of this submission. Functional testing was conducted both in-house and by medical physicists/dosimetrists at Auburn University. These tests have demonstrated that Puma has met its predetermined specifications, is substantially equivalent in performance as compared to the predicate devices, functions as intended, and is safe and effective for its specified use.

9. Summary of Clinical Tests

Although clinical testing is not required to demonstrate substantial equivalence in safety and effectiveness, we elected to conduct testing at Auburn University using real patient cases. We feel that

no matter how carefully a product is tested at the manufacturer's facility, such testing cannot replace actual use of the device in a clinical setting. As such, we consider both in-house testing and beta testing at a user site during device development.

10. Labeling

The CD media labeling, Instructions for Use and User Manual are provided in Section VI of this submission. The entire User Manual, in digital format, is also included in the software media and can be viewed as part of the on-line help.

Commercial and marketing materials are also included in Section VI.

Product labels comply with 21 CFR 1040.10 and 1040.11 as applicable. In addition, labeling complies with applicable requirements of 21 CFR 801, including the requirement that the device be provided with adequate directions for use.

11. Summary of Safety and Effectiveness Information

a. Prowess, Inc. is a registered medical device establishment, whose quality system meets the requirements of ISO 13485, the Medical Device Directive 93/42/EEC Annex II and FDA's Quality System Regulation, 21 CFR 820.

b. Puma was designed and implemented according to the established design and development as well as quality management procedures of Prowess Inc. In addition, design and development of the medical device software complies with internationally recognized standards including ISO 14971:2007Medical devices – Application of risk management to medical devices, IEC 62304 Medical device software – Software life cycle processes, and IEC 62274 Medical electrical equipment – Safety of radiotherapy record and verify systems.

c. The management of the company is committed to the highest standards of quality management. The Quality Management System is subject to regular, planned and documented audits by external consultants and by the FDA.

d. A comprehensive risk analysis has been conducted. Detailed methods of mitigating these potential risks have been identified by the development team, and verified by clinical physicists contracted by Prowess and determined to be adequate.

e. The software has been verified and validated based on established testing plans. The functionalities have been tested by in-house test engineers. In addition to in-house testing, the system was also tested by our beta-site using clinical cases. Documentation of these tests is included in Section IX of the submission.

f. Key safety features of Puma include

- Defined privileges to access specified areas of the functionality for different roles and users
- Patient identification by an ID photo associated to the patient during registration
- Data locking and messaging to prevent simultaneous access to patient treatment data
- Verifying that the beams contained in the treatment plan are correctly set up on the linear accelerator

g. Puma includes features specifically designed to protect confidential patient health information in accordance with the HIPAA regulations, including such security measures as

password protection and access privilege set up and modification. By restricting access and other rights, patient health information can be safeguarded against deletion and/or alteration.

h. Steps and precautions for the safe and effective use are included in the Instructions for Use and User Manual. Training by a Prowess specialist may also be provided as at the time of product distribution, when requested by the customer.

12. Level of Concern

As medical device software, the submission for Puma follows FDA's *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.* Since prior to mitigation of hazards, a failure of the software device could result in death or serious injury to a patient, it has been determined that the software correlates to a Major Level of Concern, and as such, the associated documentation is included in this submission.

13. Conclusions

Puma is substantially equivalent to the predicate devices for the purposes of FDA clearance for commercial distribution. It has the same intended use and similar technical characteristics. The software has been found to perform as intended and the benefits to patient and user outweigh any inherent risks, which has been demonstrated via in-house testing as well as in our field tests. Its use does not raise any new or different safety and effectiveness concerns when compared to the predicate

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

JUN 18 2010

Ms. Rachel Scarano
Regulatory Affairs Manager
Prowess, Inc.
1844 Clayton Road
CONCORD CA 94520

Re: K100801
Trade/Device Name: Puma
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: May 27, 2010
Received: June 1, 2010

Dear Mr. Scarano:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K100801

Device Name: Puma

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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